

K052086 1.71

AUG 31 2005

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name:

Encore® Reverse® Shoulder Prosthesis (RSP)

Common Name:

Cemented semi-constrained total shoulder

Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Indications:

The Encore Reverse Shoulder Prosthesis (RSP) is intended for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

During primary surgery, after the humerus is prepared for the RSP humeral stem, if the glenoid bone stock appears "insufficient" to bear the load of the glenoid baseplate, a RSP humeral stem adapter can be used to convert the RSP humeral stem to a hemiarthroplasty prosthesis.

During revision surgery of an RSP, if the glenoid bone stock appears to be "insufficient" to bear the load of the glenoid baseplate device; a RSP Humeral Stem Adapter is used to convert the RSP device to a hemiarthroplasty prosthesis.

Description:

The Encore Reverse Shoulder Prosthesis (RSP) is indicated for salvage procedures for irreparable rotator cuff, failed hemi or total shoulder arthroplasty with irreparable rotator cuff, and for fracture in which the tuberosity and rotator cuff are irreparable. Unlike traditional total shoulders, the RSP is designed so that the "ball" of the articulation fits into the glenoid baseplate, and the "cup" of the articulation fits into a metal cup attached to the humeral stem.

The RSP Humeral Stem Adapter is used to convert the RSP to a hemiarthroplasty when the glenoid bone stock appears to be "insufficient" to bear the load of the glenoid baseplate device. There is no change to the intended use or fundamental scientific technology of the RSP with the modifications in this Special 510(k) submission.

Substantial Equivalence

The modified Encore RSP is similar in design, materials, and intended use to the previously cleared Encore RSP devices, K041066 and K051075.



AUG 31 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christie Shumaker
Encore Medical, L.P.
9800 Metric Boulevard
Austin, Texas 78758

Re: K052086

Trade/Device Name: Encore Reverse Shoulder Prosthesis® (RSP)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: August 1, 2005
Received: August 3, 2005

Dear Ms. Shumaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

141

Indications for Use

510(k) Number (if known): K052086

Device Name: Encore Reverse Shoulder Prosthesis® (RSP)

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K052086